

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (JLH)
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**NS'S MEMORANDUM OF LAW IN SUPPORT OF ITS RESPONSE TO
SAREPTA AND UWA'S MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 1
REGARDING INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590**

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60601
Telephone: 312.324.1000 | Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Amy M. Dudash (DE Bar No. 5741)
MORGAN, LEWIS & BOCKIUS LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000 | Fax: 302.574.3001
amy.dudash@morganlewis.com

Alison P. Patitucci (admitted *pro hac vice*)
2222 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000 | Fax: 215.963.5001
alison.patitucci@morganlewis.com

*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

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I INTRODUCTION

The Court should deny Sarepta Therapeutics, Inc. and the University of Western Australia's (together, "Sarepta's") motion for summary judgment of U.S. Patent Nos. 9,994,851 ("the '851 Patent") and 10,227,590 ("the '590 Patent") because the undisputed material facts demonstrate that accused product, viltolarsen, does not meet each limitation of the claims. Specifically, viltolarsen is an antisense oligonucleotide with a base sequence that contains a specific sequence of bases from SEQ ID NO: 195—CCT CCG GTT CTG AAG GTG TTC. Each asserted claim require that the accused product includes an "antisense oligonucleotide . . . wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195)." NS Ex. 49, Esau Rebuttal, ¶¶ 27, 59. A simple review of viltolarsen's base sequence shows that it does not include "at least 12 consecutive bases" of the listed SEQ ID NO: 195. *Id.*

Sarepta argues that viltolarsen infringes because it meets another limitation, which requires that "the antisense oligonucleotide has thymine bases instead of uracil bases." D.I. 409 at 4-7. However, infringement requires that viltolarsen meet each and every limitation of the claim. The additional "thymine bases" limitation does not absolve Sarepta of proving that viltolarsen also meets the limitation requiring "at least 12 consecutive bases" of the listed SEQ ID NO: 195. Sarepta further argues that Nippon Shinyaku and NS Pharma (collectively, "NS") have improperly applied the Court's claim construction with respect to the "thymine bases" limitation. However, it is Sarepta's analysis that is expressly contradictory to the Court's construction—the same construction that Sarepta itself asserted. Since the undisputed facts demonstrate that NS's accused product does not meet each limitation of the claims, Sarepta's motion must be denied. In fact, given that there is no material fact in dispute, the Court should grant summary judgment of no infringement in favor of NS pursuant to Fed. R. Civ. P. 56(f).

II CONCISE STATEMENT OF FACTS

NS incorporates by reference its concise statement of facts (“SOF”) filed contemporaneously herewith.

III ARGUMENT

It is black letter law that patent infringement requires the infringer to practice *every limitation* of the asserted claims. *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001) (“An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents.”). Thus, if even a single limitation is missing, there is no infringement. *Id.* As described below, the base sequence of NS’s viltolarsen product is not in dispute, and the correct comparison of that base sequence to the claims asserted by Sarepta shows that viltolarsen does not meet every limitation of the asserted claims. Accordingly, Sarepta’s motion must be denied, and the Court should instead enter summary judgement of no infringement pursuant to Fed. R. Civ. P. 56(f).

A. There is No Dispute Regarding the Base Sequence of Viltolarsen

Despite the central nature of the base sequence of viltolarsen (the antisense oligonucleotide contained in NS’s Viltepso® product) to Sarepta’s argument, Sarepta did not include the recitation of that base sequence as one of its undisputed facts, nor did Sarepta ever recite the viltolarsen base sequence in its memorandum. *See* D.I. 409, 411. Presumably, Sarepta recognized that even a lay person could compare the base sequence of viltolarsen to the claim limitations and would realize that viltolarsen does not meet the limitations. Nonetheless, the base sequence of viltolarsen is undisputed. Viltolarsen is an antisense oligonucleotide with 21 bases: “CCTCCGGTTC TGAAGGTGTT C.” NS’s Statement of Facts in Opposition to MSJ No. 1 (“NS Opp.’n SOF”), ¶ 1.

B. Each of the Asserted Claims Requires An Antisense Oligonucleotide Having a Base Sequence that Comprises at Least 12 Consecutive Bases of SEQ ID NO: 195

The claims of U.S. Patent Nos. 9,994,851 (“the ’851 Patent”), 10,227,590 (“the ’590 Patent”), and 10,266,827 (“the ’827 Patent”) (collectively, the “UWA Patents”)¹ all include limitations directed to an antisense oligonucleotide having certain characteristics. NS Opp’n SOF, ¶ 2. Each claim includes the limitation requiring that the antisense oligonucleotide have a base sequence “wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195).” See NS Opp’n SOF, ¶ 3.² As NS’s expert, Dr. Christine Esau, explained in her expert report, the base sequence of viltolarsen does not include “at least 12 consecutive bases of ... SEQ ID NO: 195”:

SEQ ID NO: 195 and the Base Sequence of Viltolarsen	
SEQ ID NO: 195	5' - CUGAAGGUGUUCUUGUACUUCAUCC -3' X X XX
Viltolarsen	5' -CCTCCGGTTCTGAAGGTGTTTC-3'

NS Ex. 49, Esau Rebuttal ¶ 32. This simple analysis confirms that viltolarsen does not meet every limitation of claims of the UWA Patents and that summary judgment of no infringement is warranted. *Gart*, 254 F.3d at 1339.

C. Sarepta’s Analysis Requires Modifying SEQ ID NO. 195

¹ Sarepta’s motion only addresses the ’590 and ’827 Patents, not the ’827 Patent, presumably because the ’827 Patent is directed to a method of treatment (rather than a product) that Sarepta alleges is indirectly infringed by NS, and *there is a disputed fact regarding NS’s alleged knowledge of infringement that precludes summary judgment*. Nonetheless, since the ’827 Patent includes the same limitations at issue in this motion, NS includes it in the discussion here.

² Claim 2 of the ’827 Patent does not literally include the quoted language, but claim 2 depends from claim 1, which does include the quoted language. NS Opp’n SOF, ¶ 3 n.1.

Instead of applying the plain and ordinary meaning of the 12 consecutive bases limitation, Sarepta attempts to argue infringement by modifying SEQ ID NO: 195 in the claims to replace the uracil (“U”) bases in SEQ ID NO: 195 with thymine (“T”) bases prior to conducting its analysis:

SEQ ID NO: 195 and the Base Sequence of Viltolarsen	
SEQ ID NO: 195	5' - CUGAAGGUGUUUCUUGUACUUCAUCC - 3'
12 Bases from SEQ ID NO: 195	CTGAAGGTGTTC
Viltolarsen	5' - CCTCCGGTTCTGAAGGTGTTC - 3'

Table 10. SEQ ID NO: 195 of the Wilton Patents and Viltolarsen

Re-writing the “SEQ ID NO: 195” with thymine bases instead of uracil bases.

NS Ex. 49, Esau Rebuttal ¶ 34; *see also* NS Ex. 1, Dowdy Opening ¶¶ 251-253. Sarepta’s analysis is not consistent with the plain and ordinary meaning of the 12 consecutive bases limitation and must be rejected.

D. Sarepta’s Analysis Directly Contradicts the Court’s Claim Construction

In order to support its motion, Sarepta argues that its analysis is based on its interpretation of the Court’s claim construction. Specifically, each of the UWA patents includes a clause: “in which uracil bases are thymine bases.” *See* Sarepta Exs. 1-3 at Claims 1-2. The Court construed this clause to mean that “the antisense oligonucleotide has thymine bases instead of uracil bases.” D.I. 249. NS does not dispute that viltolarsen is an antisense oligonucleotide that has thymine bases instead of uracil bases. However, Sarepta’s analysis ignores the requirement that viltolarsen has a base sequence comprising “at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195).” NS Ex. 49, Esau Rebuttal ¶¶ 27, 59. Instead of applying the thymine bases limitation to the antisense oligonucleotide as a whole, Sarepta asserts the “in which uracil bases are thymine bases” clause serves to modify SEQ ID NO: 195—replacing the uracil bases of SEQ ID NO: 195 with thymine bases. *Id.* ¶ 34; *see also* NS Ex. 1, Dowdy Opening

Report ¶ 251-253. This analysis directly contradicts the Court’s claim construction and cannot stand. *See Cryovac Inc. v. Pechiney Plastic Packaging, Inc.*, 430 F. Supp. 2d 346, 353-54 (D. Del. 2006) (granting summary judgment when the accused party’s analysis was based on a claim construction not adopted by the court).

In fact, Sarepta’s infringement arguments are precluded by the doctrines of waiver and judicial estoppel. A party waives the right to challenge claim construction “by agreeing to that portion of the adopted construction.” *Abbott Lab’ys v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1352 (Fed. Cir. 2003). Similarly, “[t]he doctrine of judicial estoppel [applies] where a party successfully urges a particular position in a legal proceeding, [such that] it is estopped from [later] taking a contrary position.” *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996). “Courts have applied this doctrine to prevent parties from later raising issues that they conceded or agreed to as part of the earlier claim construction.” *Wonderland Switzerland AG v. Evenflo Co.*, No. 1:20-cv-00727-JPM, 2022 U.S. Dist. LEXIS 244560, at *15 (D. Del. Dec. 6, 2022).

Here, during claim construction proceedings, Sarepta itself argued for the claim construction that was adopted by the Court and specifically argued against a claim construction in line with the analysis it now conducts.

At the outset, the parties disputed the appropriate construction of the “in which uracil bases are thymine bases” phrase and identified two potential constructions: (1) the phrase modifies “antisense oligonucleotide” as a whole, or (2) the phrase modifies SEQ ID NO: 195 (the sequence of bases immediately preceding the disputed phrase). *See* D.I. 166, NS Ex. 25, Joint Claim Constr. Br. for the Wilton/UWA Patents at 48; *see also* NS Ex. 50, Claim Constr. Hr’g Tr. at 55:17-56:13.

During the briefing, the parties reformatted the claims to show the application of the two potential constructions:

Sarepta's Formatting	NS's Formatting
<p>1. An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA,</p> <p>wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195),</p> <p>in which uracil bases are thymine bases,</p> <p>wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and</p> <p>wherein the antisense oligonucleotide induces exon 53 skipping;</p> <p>or a pharmaceutically acceptable salt thereof.</p>	<p>1. An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA,</p> <p>wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases,</p> <p>wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and</p> <p>wherein the antisense oligonucleotide induces exon 53 skipping;</p> <p>or a pharmaceutically acceptable salt thereof.</p>

D.I. 166, NS Ex. 25, Joint Claim Constr. Br. for the Wilton/UWA Patents at 57.

Throughout claim construction, both parties understood that, under Sarepta's formatting, the thymine bases limitation was a "separate limitation" that modified the "claimed antisense oligonucleotide as a whole." *Id.* at 43 (the disputed phrase "must be read as a separate limitation"); 45, 57-58 (explaining that the 12 consecutive bases limitation and thymine bases limitation "are independent, each modifying the claimed antisense oligonucleotide"); 61 ("independently modifies the claimed antisense oligonucleotide as a whole."). Alternatively, under NS's formatting, the disputed limitation replaced the uracil bases in SEQ ID NO: 195 with thymine bases. D.I. 166, NS Ex. 25, Joint Claim Constr. Br. for the Wilton/UWA Patents at 48; D.I. 171, NS Ex. 51, J.A. for the Wilton/UWA Patents at Ex. 43, ¶ 101 ("namely that the uracil bases of the specifically recited SEQ ID NO: 195 are replaced with thymine bases in the claims"); NS Ex. 50, Claim Constr. Hr'g Tr. at 61:2-13.

Similarly, throughout claim construction, Sarepta argued that the only possible interpretation was that the thymine bases limitation modified the antisense oligonucleotide as a

whole—it could not modify SEQ ID NO: 195. Joint Claim Constr. Br. for the Wilton/UWA Patents at 43, 59 (“[T]he phrase is separated from SEQ ID NO: 195 by a comma. Had it been modifying that clause only, there would have been no need to include that comma.”); NS Ex. 50, Claim Constr. Hr’g Tr. at 55:17-56:13.

Ultimately, the Court agreed with Sarepta and found that the thymine bases limitation was a separate limitation from the 12 consecutive bases limitation that modified the antisense oligonucleotide as a whole:

The plain language of the claim uses commas to set off each “wherein” and “in which” clause, **suggesting that the “in which uracil bases are thymine bases” term modifies the antecedent subject “an antisense oligonucleotide.”** ... Moreover, if the “in which uracil bases are thymine bases” term modified the sequence of bases immediately preceding it, i.e., SEQ ID NO: 195, as NS contends, then **there would be no reason the patentee used a comma to separate the “in which uracil bases are thymine bases” term from the rest of the claim language.**”

D.I. 248 at 26-27 (emphasis added); *see also id.* at 28 (noting the “distinct nature” of the thymine bases clause which demonstrates that it “independently modifies the antecedent subject ‘an antisense oligonucleotide’ as a whole rather than a feature of the preceding ‘base sequence’ limitation”).

Sarepta’s infringement analysis improperly ignores its own claim construction arguments and the Court’s claim construction ruling. Indeed, instead of treating the 12 consecutive bases limitation and the thymine bases limitation as separate and independent limitation, Sarepta unabashedly attempts to combine them into a single limitation in direct contravention of the Court’s claim construction. *See* D.I. 411 at SOF 1.10 (“Viltepso® has at least 12 consecutive bases of SEQ ID NO: 195 in which the uracil bases are thymine bases.”); *see also* NS Ex. 1, Dowdy Opening at ¶ 116 (combining the two limitations into a single limitation for purposes of analyzing infringement). Similarly, Sarepta’s analysis uses the thymine bases limitation to modify SEQ ID

NO: 195, again in direct contravention of the Court’s claim construction. NS Ex. 49, Esau Rebuttal ¶ 34; *see also* NS Ex. 1 Dowdy Opening at ¶¶ 251-253.

Since the analysis used by Sarepta to support its infringement arguments is inconsistent with the Court’s claim construction, and since Sarepta is precluded from asserting such analysis under the doctrine of waiver and estoppel, Sarepta’s motion must be denied.

E. Sarepta’s Arguments For Avoiding the Proper Analysis Are Without Merit

Sarepta’s motion includes two additional arguments as to why the Court should ignore NS’s analysis. First, Sarepta argues that NS’s analysis should be rejected because it leads to an impossibility. D.I. 409 at 6. Second, Sarepta argues that NS’s analysis should be rejected because another NS expert—Dr. Hastings—conducted her analysis consistent with Sarepta’s position. *Id.* at 6-7. Neither argument has merit.

First, NS agrees that the Court’s claim construction of the thymine bases limitation renders the claims of the UWA Patents indefinite due to impossibility. Specifically, under the Court’s claim construction, the claimed antisense oligonucleotide is required to:

- have a base sequence “wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195)”; and
- include “thymine bases instead of uracil bases.”

D.I. 248 at 8, 29. The Court expressly found that each of these limitations were “distinct” and “independent” limitations of the antisense oligonucleotide. D.I. 248 at 28. Since every set of 12 consecutive bases of SEQ ID NO: 195 includes at least one uracil base, it is impossible for an antisense oligonucleotide to simultaneously meet both limitations. However, this is no reason for the Court to adopt Sarepta’s analysis. Instead, since it is impossible to meet both limitations simultaneously, the Court should find the claims of the UWA Patents invalid as indefinite. *Synchronoss Techs., Inc. v. Dropbox, Inc.*, 987 F.3d 1358, 1366-67 (Fed. Cir. 2021) (holding

claims invalid as the claims were “nonsensical and require[ed] an impossibility”); *Koki Holdings Co. v. Kyocera Senco Indus. Tools, Inc.*, No. 18-313-CFC, 2021 WL 1092579, at *2 (D. Del. Mar. 22, 2021) (claims that “require a physical impossibility … are inherently unclear and cannot provide ‘reasonable certainty about the scope of the invention’”).

Sarepta argues that “when claim language permits an operable construction, an inoperable construction is wrong.” D.I. 409 at 6. Here, however, the only “operable” construction requires the thymine bases limitation to modify SEQ ID NO: 195. Otherwise, the antisense oligonucleotide must meet a limitation requiring “12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C,” which necessarily includes at least one uracil base. However, as discussed above, both Sarepta and the Court have already determined that the claim language ***does not permit such a construction.*** Thus, the only way forward is to find the claims indefinite as impossible. *Koki Holdings*, 2021 WL 1092579, at *2 (“[I]t is improper to rewrite claim language to save a patent from impossibility.”).

Second, the fact that NS’s other expert, Dr. Hastings, has conducted her analysis in a manner that is inconsistent with Dr. Esau’s opinions is not relevant. Dr. Hastings was specifically asked to conduct an alternative analysis (with respect to invalidity) in the event that the Court adopted Sarepta’s view, in order to show that even if Sarepta’s view was adopted, the asserted claims of the UWA Patents are invalid. The approach of providing alternative theories—including “arguments analyzed under an opposing party’s interpretation of the claims”—has been expressly permitted by this Court and does not warrant summary judgment.

Future Link’s concerns that Intel’s infringement position is inconsistent with its licensing defense, and further, that Intel’s experts only analyzed commercialization under Future Link’s interpretation of the claims, do not entitle it to summary judgment. As the Court previously noted … such alterative arguments, and arguments analyzed under an opposing party’s interpretation of the claims, are permissible.

Intel Corp. v. Future Link Sys., LLC, 268 F. Supp. 3d 605, 614 (D. Del. 2017)

F. The Court Should Enter Summary Judgement that the UWA Patents Are Both Not Infringed and Invalid

Pursuant to Fed. R. Civ. P. 56(f), the Court has the authority to “grant summary judgment for a nonmovant” or “consider summary judgment on its own.” *Id.*; *see also CareDX, Inc. v. Natera, Inc.*, 563 F. Supp. 3d 329, 332 (D. Del. 2021); *Stored Value Sols., Inc. v. Card Activation Techs., Inc.*, 796 F. Supp. 2d 520, 539-40 (D. Del. 2011). Here, there is no disputed material fact regarding the base sequence of NS’s accused product. And, as described above, the Court’s claim construction demonstrates that (i) NS’s accused product does not meet the 12 consecutive bases limitation found in every claim of the UWA Patents, and (ii) it is impossible for any antisense oligonucleotide to meet the limitations of the UWA Patents. Summary judgment of noninfringement and invalidity are warranted.

IV CONCLUSION

For the foregoing reasons, the Court should deny Sarepta’s Motion for Summary Judgment No. 1 in its entirety and should instead enter summary judgment that NS does not infringe any claim of U.S. Patent Nos. 9,994,851, 10,227,590, and 10,266,827.

Dated: January 12, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary D. Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800

/s/Amy M. Dudash
Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street, Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

*Attorneys for Plaintiff/Counterclaim
Defendant Nippon Shinyaku Co., Ltd.
and Counterclaim Defendant NS
Pharma, Inc.*

Alison P. Patitucci (admitted *pro hac vice*)
2222 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
alison.patitucci@morganlewis.com